

CLAIMS

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1. A method of regulating the expression in a mammal of a nucleic acid sequence encoding a polypeptide which is immunogenic in the mammal; the method comprising introducing into the mammal a cell comprising the nucleic acid sequence encoding the immunogenic polypeptide, said sequence being operably linked to a drug-regulatable promoter; and altering the concentration of regulatory drug to which the cell is exposed.

2. The method of claim 1, in which the cell is a leukocyte.

15 3. The method of claim 1, wherein the cell is a B lymphocyte, T lymphocyte, monocyte or macrophage.

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20 4. The method of claim 1, wherein the mammal has made an immune response to the immunogenic polypeptide.

5. The method of claim 1, wherein the mammal has circulating antibodies which react with the immunogenic polypeptide.

25 6. The method of claim 1, wherein the mammal has immunocompetent memory cells which are specific for the immunogenic polypeptide.

30 7. The method of claim 1, wherein prior to introduction of the cell into the mammal the expression of the immunogenic polypeptide is substantially inhibited *in vitro*, and wherein expression of the immunogenic polypeptide reaches a maximum level in the mammal after a delay interval.

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33 8. The method of claim 7, wherein expression of the immunogenic polypeptide is inhibited *in vitro* by exposure of the cell to the regulatory drug, and wherein expression in the mammal is

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induced after a delay interval, the mammal being substantially free of the regulatory drug.

9. The method of claim 7, wherein expression of the immunogenic polypeptide is inhibited *in vitro* by substantial absence of the regulatory drug and wherein expression in the mammal is induced after a delay interval by administration to the mammal of the regulatory drug. 112 Z¹

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10. The method of claim 1, wherein the regulatory drug is selected from the group consisting of: tetracycline, glucocorticoid steroids, sex hormone steroids, lipopolysaccharide (LPS), and Isopropylthiogalactoside (IPTG).

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11. The method of claim 1, wherein the immunogenic polypeptide exerts a therapeutic effect in the mammal.

12. The method of claim 1, wherein the immunogenic polypeptide exerts an anti-tumor effect in the mammal.

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13. The method of claim 1, wherein the nucleic acid sequence encodes a replicable viral genome or a viral vector.

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14. A cell transformed with a nucleic acid sequence encoding a polypeptide which is immunogenic to a mammal, the nucleic acid sequence being operably linked to a drug-regulatable promoter, such that expression of the immunogenic polypeptide by the cell may be controlled by altering the concentration of regulatory drug to which the cell is exposed.

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15. The cell of claim 14, said cell being a leukocyte.

16. A composition comprising a plurality of a cell of claim 14, and a physiologically acceptable diluent.

17. A method of making a physiological composition, the method comprising: obtaining a sample of cells from a mammal; transforming the cells with a nucleic acid sequence encoding a heterologous immunogenic polypeptide, said nucleic acid coding sequence being operably linked to a drug-regulatable promoter; selecting those cells successfully transformed; and mixing the selected cells with a physiologically acceptable diluent.

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18. A method of regulating the expression of a nucleic acid sequence encoding a heterologous polypeptide in a leukocyte, comprising introducing into the leukocyte the nucleic acid coding sequence operably-linked to a tetracycline-operator sequence, and a sequence encoding a tetracycline-sensitive DNA-binding expression-regulating polypeptide; and altering the concentration of tetracycline (or analogues thereof) to which the leukocyte is exposed, so as to regulate expression of the coding sequence.

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